UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOUCEBERGEN DRUG CORPORATION, *et al.* Defendants	Civil Action No. 3:17-01362
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOUCEBERGEN DRUG CORPORATION, *et al.* Defendants	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' *DAUBERT* MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI

October 23, 2020

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INTRODUCTION

Plaintiffs submit this memorandum in opposition to Defendants' Motion to Exclude the Opinions Offered by James Rafalski (Dkt. # 1900). Defendants seek to exclude Mr. Rafalski's testimony for a grab-bag of reasons, most of which were rejected by Judge Polster in the MDL.[1] This Court should do the same. Mr. Rafalski does offer one new opinion not addressed by Judge Polster, but Defendants' challenges to that opinion are not well-taken and should be rejected as well.

Mr. Rafalski is a former Drug Enforcement Administration Diversion Investigator with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act ("CSA") and to the suspicious order monitoring ("SOM") programs that opioid distributors like Defendants are required to maintain in order to provide effective controls against diversion. Based on his DEA and other law enforcement experience, he assesses the SOM programs purportedly used by the Defendants and identifies their systemic flaws. He describes six different methodologies that could have been used to identify suspicious orders that should not have been shipped without further diligence and assesses the results of applying those methodologies to the orders Defendants in fact shipped into West Virginia. These opinions are analogous to the opinions Mr. Rafalski offered in the MDL and that were upheld by Judge Polster.

Based on his DEA experience, Mr. Rafalski also opines about whether orders that should not have been shipped without due diligence were likely to be diverted. He does *not*, however, offer opinions about the number of orders that were *in fact* diverted, nor is he required to do so. Plaintiffs have other evidence that diversion in fact occurred; the opinions of Mr. Rafalski

[1] James Rafalski was the subject of a *Daubert* motion filed in the MDL Court. Judge Polster Denied the *Daubert* Motion. *See* Ex. 1, Opinion and Order Regarding Defendants' Motions to Exclude Opinions of James Rafalski and Craig McCann, Dkt. # 2494.

regarding the astonishingly high percentage of suspicious orders that were shipped without appropriate due diligence show that Defendants did not have sufficient controls to prevent diversion, thereby predictably leading to a large quantity of opioids entering the illicit market.

Mr. Rafalski thus provides valuable evidence about Defendants' shipment of massive quantities of opioids to West Virginia without the due diligence required to guard against diversion, and about their failure to comply with their legal obligations to maintain effective controls against diversion. As demonstrated below, these opinions are within his expertise, are reliable and methodologically sound, and are tailored to the facts of this case. Defendants' motion to exclude them should be denied in its entirety.

LEGAL STANDARD

Plaintiffs incorporate by reference the statement of the legal standard made in Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude the Expert Testimony of Andrew Kolodny, filed contemporaneously herewith.

REGULATORY BACKGROUND

As described below, Mr. Rafalski's opinions pertain to the CSA regulatory scheme and to Defendants' failure to comply with it. The CSA is a comprehensive statutory scheme enacted to combat drug abuse. Its purpose was to design a "closed system" for the supply of dangerous drugs to the public and to control against the diversion of those drugs for non-medical use. In order to prevent diversion, the CSA requires anyone who manufactures, distributes, or dispenses controlled substances to register with the DEA, the agency charged with its enforcement. 21 U.S.C. § 822. The DEA is required to grant registration only where doing so is consistent with the public interest. 21 U.S.C. § 823. It is unlawful for any person knowingly to manufacture, distribute, or dispense controlled substances except in accordance with the requirements of the CSA and its implementing regulations. 21 U.S.C. § 841; *see also* 21 U.S.C. § 842. Thus, in exchange for the privilege of

trading in these dangerous substances, registrants must comply with statutory and regulatory duties to protect individuals and communities from the predictable consequences of uncontrolled use of these drugs.

The CSA regulations require that *all* registrants "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a); *see also* 21 U.S.C. § 824. Manufacturers and distributors are required to design and operate systems to identify suspicious orders (defined as orders of unusual size, frequency, or pattern), report suspicious orders to the DEA, and to halt shipment of suspicious orders unless and until it can be determined through due diligence that such orders are unlikely to be diverted. *See* 21 C.F.R. § 1301.74; *see also In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *7 (citing *Masters Pharm., Inc. v. DEA ("Masters II")*, 861 F.3d 206, 212 (D.C. Cir. 2017). Indeed, in the MDL, Judge Polster noted that he was "hard-pressed to think of a more basic requirement" than the requirement to halt shipment of suspicious orders pending due diligence:

> How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.

Id.

Plaintiffs allege, however, that Defendants failed to identify suspicious orders and failed to perform the requisite due diligence before shipping out orders they should have flagged as suspicious. Mr. Rafalski offers expert opinions supporting Plaintiffs' contention that Defendants failed to comply with their obligations under the CSA and about the likelihood that their failure to comply led to diversion.

MR. RAFALSKI AND HIS OPINIONS

Defendants do not challenge Mr. Rafalski's qualifications to offer his opinions. Plaintiffs note, however, that Mr. Rafalski has 26 years of law enforcement experience, including 13 years

of experience as a diversion investigator for the DEA.[2] He is knowledgeable about the federal laws and regulations governing the distribution of controlled substances, and has extensive training and experience relating to suspicious order monitoring, data analysis from ARCOS, reporting of suspicious orders, and the due diligence required before shipping an order flagged as suspicious.[3] Mr. Rafalski has also participated in multiple major investigations and prosecutions related to diversion prevention and suspicious order monitoring.[4] The experience and methods that Mr. Rafalski utilized in his prior investigations are the same that he is using for his expert report.

The Rafalski Report provides a detailed discussion of the federal regulatory regime governing the distribution of controlled substances, a regulatory regime that he is extremely familiar with given his work for the DEA.[5] Based on the applicable regulatory requirements, and his background, Mr. Rafalski identifies key components that are generally needed to maintain effective controls against diversion.[6] Mr. Rafalski then discusses various screening methodologies that a distributor could use to identify orders that are suspicious by virtue of unusual size.[7] Mr. Rafalski opines that the Six Month Trailing Average methodology (Method A) and the Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold (Method B) are reliable methodologies for screening orders of unusual size. A view shared by the D.C. Circuit after review of the system upon which Method A is based.[8] He also identifies several methodologies that are

[2] Expert App'x, Dkt. # 1097, Exh. 10-A at 4; 7 (Rafalski Rpt.).

[3] *Id*.

[4] *Id.* 5-6.

[5] *Id.* at 9-47.

[6] *Id.* at 42 - 47.

[7] *Id.* at 47-55.

[8] *Id*. at 50-51; *See Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 212-213 (D.C. Cir. 2017).

similar to the ones that Defendants purportedly employed but failed to actually execute.[9] Using the methodologies identified by Mr. Rafalski, Dr. Craig McCann, another expert disclosed by Plaintiffs, analyzed data reflecting each shipment of opioids Defendants made to West Virginia and flagged orders that would have been noted as "suspicious" under each of the methodologies. Mr. Rafalski then reviewed and analyzed Dr. McCann's results to provide an estimate of the number of orders that should have been flagged by Defendants as suspicious, and held pending investigation, but that Defendants shipped to Huntington and Cabell County. Mr. Rafalski also evaluates the SOM programs used by the different Defendants based on the depositions taken and documents produced by these Defendants in discovery. Based on this review, Mr. Rafalski opines that Defendants failed to maintain effective controls against diversion, including the adequacy of the due diligence performed by Defendants on suspicious orders.

The above opinions were all expressly permitted in the MDL by Judge Polster, who found Mr. Rafalski's methodologies to be reliable and determined that they would aid the trier of fact.[10] The only limitation placed by Judge Polster on Mr. Rafalski's concerned "opinions as to what the law requires, or whether Defendants' conduct violated the law," which is not at issue here, as Mr. Rafalski does not plan offer any such opinions in this case.

Finally, Mr. Rafalski offers an additional opinion not offered in the case before Judge Polster: based on Mr. Rafalski's education, background, experience, and on his review of Defendants' documents and conduct, including those evidencing Defendants' lack of effective controls to prevent diversion and systemic failure to conduct due diligence, that it was more likely than not that flagged orders regarding which Defendants did not conduct due diligence would be

[9] *Id*. at 48-50.

[10] *See* Ex. 1 at 12.

diverted.

ARGUMENT

I. THE METHODOLOGIES IDENTIFIED BY MR. RAFALSKI ARE RELIABLE

Mr. Rafalski's report identifies six methodologies that could have been used to identify suspicious orders (Methodology A-F).[11] All of these methodologies are reliable bases for Mr. Rafalski's opinions because they were either endorsed by the D.C. Circuit or were used by Defendants themselves. Judge Polster has already considered and rejected the arguments made by Defendants here:

> As this Court has previously found, an order may be suspicious for any number of reasons, and there are many algorithms that a Distributor could use to identify opioid orders as suspicious. Discovery Ruling no. 12 ("DR-12") at 2-3, n.2 (Doc. #: 1174); *see also* Order denying Daubert motion seeking to exclude Keller. Based on Rafalski's extensive field experience as a DEA investigator reviewing the effectiveness of Distributors' SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable. *See First Tennessee Bank Nat'l Ass'n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (where non-scientific expert testimony is involved, the relevant reliability concerns may focus on personal knowledge or experience). Moreover, in determining whether Defendants employed effective measures to identify, investigate, and stop shipment of suspicious orders, it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged. Accordingly, the Court concludes that Rafalski's methodologies are reliable and would aid the jury's determination of material issues in the case.

In re National Prescription Opiate Litigation, 2019 WL 3934490, at *6 (N.D. Ohio, Aug. 20, 2019). Contrary to Defendants' arguments, each of Mr. Rafalski's six methodologies provides an appropriate basis for assessing the extent to which Defendants shipped opioids to Cabell and Huntington without performed the due diligence that is required under the CSA.

A. Methods A and B

1. Method A - Maximum Monthly, Trailing Six-month Threshold

Method A identifies transactions that cause the number of dosage units shipped by a

[11] Expert App'x, Dkt. # 1097, Exh. 10-A at 47-52 (Rafalski Rpt.).

distributor to a pharmacy in a calendar month to exceed the highest number of dosage units shipped by that distributor to that pharmacy in any one of the six preceding calendar months. This method is founded on the volume-based portion of the test set forth in *Masters Pharmaceutical, Inc. v. Drug Enforcement Admin.*[12] In *Masters*, the D.C. Circuit upheld a DEA decision revoking the registration of Masters, a distributor of controlled substances to pharmacies, where the distributor shipped flagged orders without performing due diligence. The court considered Masters' SOMS Computer Program which flagged orders (or sets of orders) where:

> (a) an order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months;
>
> (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months; *or*
>
> (c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months.[13]

The D.C. Circuit concluded that the above methodology identified suspicious orders of unusual size, emphasizing that "[a]s a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence."[14] The D.C. Circuit also held that, without due diligence, these orders could not legally be shipped.[15] Notably, nothing in the court's decision indicated that the above methodology was appropriate for use only by Masters; in fact, the decision focused on the statutory language of the CSA and the methodology's ability to satisfy the statutory command. Given that this methodology was approved by a federal appellate court as an appropriate means for identifying suspicious orders, there is nothing unreliable about applying it generally to a wide range of registrants.

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[12] 861 F.3d 206 (D.C. Cir. 2017).

[13] *Id.* at 216

[14] *Id*.

[15] *Id.* at 222-23.

2. Method B - Trailing Six-month Maximum Monthly, Fixed After First Triggered Threshold

This method identifies transactions that cause the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to that pharmacy in any one of the six preceding months. When a transaction meeting these parameters is identified, the dosage units of the highest month in the preceding six months becomes the threshold which is then applied in all subsequent months. This method is a slight variation on the *Masters* method employed in Method A. Like Method A, this method is based on the volume-based portion of the test set forth in *Masters.*[16] Method A compares the cumulative shipments in a drug code to the maximum of the trailing six calendar months and once an order is flagged all subsequent orders are flagged. Method B applies the maximum of whatever the trailing six calendar months was at the time that the first order was flagged and establishes that as a threshold and flags shipments on any day that would cause the cumulative total for that month to exceed this threshold and all additional orders the rest of the month that would flag that threshold.[17]

B. Methods Based on Those Used by Defendants

1. Method C - Twice Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to pharmacies served by the distributor. The method is a variant of Appendix E-3 of the Chemical Handler's Manual ("Appendix E-3"), which is explained below.

2. Method D - Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a

[16] *Id.* at 206.

[17] Ex. 2 McCann Dep. Sept. 1, 2020 at 24:18–25:10

distributor to a pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to pharmacies served by the Distributor. The method is based on Appendix E-3,[18] with some minor adjustments. These guidelines contained in this manual relate to "Listed Chemicals" and are primarily focused on the sale of chemicals used to make illicit methamphetamine. These chemicals are also subject to a separate, and less stringent, suspicious order reporting requirement. In contrast to the suspicious order definition for the more strictly regulated Schedule II and Schedule III controlled substances (which hinges on orders of "unusual" size, pattern, or frequency), the "suspicious orders" of Listed Chemicals are defined by 21 U.S.C. § 830(b)(1)(A) as orders of "extraordinary" size.[19]

Appendix E-3 outlines "a voluntary formula for use by distributors [of Listed Chemicals] to wholesale and retail levels."[20] The formula sets threshold purchase levels based on the last twelve months purchases by the same customer type from the same distribution center (e.g., the customer group).[21] That amount is divided by the total number of customer months (months in which purchases are above zero) and multiplied by a factor to determine the maximum amount a customer may purchase.[22] According to the Manual, the "[f]actor equals 3 for C-II and C-III Controlled Substances **containing List I Chemicals** and 8 for C-III-IV-V Controlled Substances and non- Controlled OTC products **containing List I chemical items**."[23]

Both Cardinal and ABDC used a variation of the formula in Appendix E-3 (or some variant

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[18] *See* Ex. 3, U.S. DEP'T OF JUSTICE, DRUG ENF'T ADMIN. CHEMICAL HANDLER'S MANUAL, (Jan. 2004) ("Chemical Handlers Manual, 2004 Edition") at Appendix E-3 WAGMDL00395965.

[19] The Chemical Handler's Manual guidelines only address Schedule II and Schedule III controlled substances to the extent those substances also contain Listed Chemicals.

[20] *Id*.

[21] *Id*.

[22] *Id*.

[23] *Id.* (emphasis added).

of that formula) for all or part of their SOM systems at varying times. For example, Cardinal Health's "Process to Establish SOM Threshold Limits"[24] set thresholds by, *inter alia*, differentiating customers through segmentation by size and/or specialty and evaluating historical controlled substance sales data per drug family, per month or each customer segment to establish appropriate threshold limits, using the multiples of 3, 5, or 8.[25] ABDC employed a threshold-based system that applied a multiplier of three to a customer's average purchases.[26]

3. Method E - Maximum 8,000 Dosage Units Monthly

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed 8,000 dosage units. The method is based on a policy in place at McKesson Corporation. In May 2007, McKesson launched the Lifestyle Drug Monitoring Program (hereinafter "LDMP").[27] The LDMP was limited to four drug products (oxycodone, hydrocodone, alprazolam and phentermine).[28] For these four drugs, an 8,000 monthly dosage unit threshold was set for every customer nationwide.[29]

4. Method F - Maximum Daily Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation. The method is based on a policy in place at Cardinal Health from the early 1990s until at least 2008 and is outlined in Cardinal Health's DEA

[24] Ex. 4, CAH_MDL_PRIORPROD_AG_0004208.

[25] *See* Ex. 5, CAH_MDL_PRIORPROD_HOUSE_0003331 at 345 (Board of Directors of Cardinal Health, Inc., *Investigation Report of the Special Demand Committee,* Apr. 12, 2013).

[26] *See* Ex. 6, Zimmerman Dep., Aug. 3, 2018, Dkt. # 1972-16 at 121:12-21; 122:18-23.

[27] Ex. 7, MCKMDL00355251.

[28] *Id.*

[29] *Id.*

Compliance Manual.[30] Cardinal's manual, under the heading "Required Reports to DEA," states as follows:

> Complying with 21 CFR 1301.74 (b) is a two-step process. First, each Cardinal Division submits to DEA on a monthly basis an Ingredient Limit Report (Exhibit M). This report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.
>
> Second, on a daily basis cage and vault personnel should be policing and identifying individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history. In these situations, DEA should be notified, if possible, before the order is shipped and a copy of all such orders should be maintained in the division's suspicious order file along with a Regulatory Agency Contact Form (Form #1) noting any specific instructions from DEA.
>
> In an effort to assist cage and vault personnel in identifying these orders, we have developed Dosage Limit Charts (Exhibit P). The products included on these charts are those commonly audited by DEA during their inspections of our facilities, and those which have a high potential for diversion. The dosage limits were set by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customer and multiplying by 3 for ARCOS reportable items and 5 for non-ARCOS items.[31]

The Dosage Limit Charts contained in Exhibit P are entitled "Excessive Purchases Schedule II" and "Excessive Purchases Schedule III, IV, V" and provide the dosage units Cardinal used to identify transactions pursuant to this methodology.[32]

C. Defendants' Attacks on the Use of the Six Methodologies Are Unfounded

1. Defendants Fail to Identify Any Flaw in the Methodologies

As the above discussion makes clear, all of these methodologies are reliable methodologies.[33] The reliability of Methods A and B has been confirmed by the D.C. Circuit, the

[30] Ex. 8, CAH_MDL_PRIORPROD_DEA07_01383895.

[31] *Id.* at 01383939.

[32] *Id.* at 01384160-01384161.

[33] Mr. Rafalski does not opine, and Plaintiffs do not concede, that any of these metrics necessarily would have satisfied Defendants' obligations. However, these methodologies are reliable to identify at least some orders of unusual size. To the extent that some or all of these algorithms significantly undercount "suspicious orders," the Rafalski analysis shows the large number of orders that would have been flagged as suspicious even under an inadequate system and thus how far below the threshold of compliance Defendants' actual conduct fell.

highest and most recent court to evaluate a SOM methodology to date. Defendants' assertions to the contrary, these methods are indeed tied to the real-world monitoring practices, in fact variations of the remaining methodologies (Methodologies C-F) *have been used by the Defendants themselves* at various times. While Mr. Rafalski declined to endorse Methodologies C-F as appropriate for a SOM program *because they would undercount suspicious orders*, they are certainly reliable methodologies for showing what Defendants would have seen had they actually applied some of the methodologies specified in their own SOM programs. As Defendants incorporated these methodologies into their SOM programs, they cannot now object and claim they are unreliable when Plaintiffs use them.

While Defendants purport to challenge the methodologies used by Mr. Rafalski, they fail to identify any actual flaw in those methodologies, other than the conclusions they generate, which Defendants claim to find "incredible."[34] But Defendants' incredulity about Mr. Rafalski's *conclusions* is a matter for cross-examination, not exclusion.[35] Moreover, Defendants' challenges to Mr. Rafalski's methodologies are based on mischaracterizations of his opinions and of the requirements of the CSA. As they have done elsewhere, Defendants conflate "suspicious orders," a technical term with a defined meaning in the law, with orders likely to be diverted. Mr. Rafalski offers opinions about the numbers of orders Defendants shipped that should have been flagged as "suspicious" under the law and should have triggered the due diligence investigations that Defendants never conducted. The likelihood that those suspicious orders would be diverted is the subject of the separate, supplemental, opinion offered by Mr. Rafalski and is distinct from the question of which orders Defendants were obliged to investigate before shipping.

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[34] *See,* Memo in Support of Motion to Exclude Rafalski Dkt. 1053 at 16.

[35] *See Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 595 (1993) ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Defendants' arguments also appear to be based on the premise that there is no reliable way to determine which orders should have been flagged as suspicious—a peculiar position given Defendants' statutory and regulatory obligation to do exactly that. But Defendants' failure to perform their legal duties should not be used as a basis to deny the Court information about the number of suspicious orders Defendants should have identified and performed due diligence on prior to shipping. This is especially true because Mr. Rafalski does not purport to identify only a single method that all Defendants should have used nor does he offer a single definitive number of "suspicious orders" that were shipped. Rather, Mr. Rafalski opines about a range of methods that might have satisfied Defendants' obligations with respect to detecting suspicious orders of unusual size, and a range for the number of orders that were shipped in violation of Defendants' duties.[36] No greater precision is required, as it is not necessary for the fact-finder to determine the precise number of such orders; the ranges provided are relevant to the Defendants' failure to maintain effective controls; the magnitude of the problem of suspicious orders; the likelihood of diversion in Cabell and Huntington; and the connection between the failure to detect, report, and halt suspicious orders and the diversion that in fact occurred. Defendants' argument poses the untenable proposition that the more ways there were to identify suspicious orders, the less Plaintiffs should be allowed to provide evidence that Defendants failed to use any of them. But the trier of fact need not proceed in the dark when multiple reliable methodologies exist to identify the suspicious orders that Defendants failed to notice. Defendants have not raised any legitimate ground for unseating Judge Polster's well-reasoned rejection of substantially the same *Daubert* challenges to Mr. Rafalski's development and use of methodologies for identifying suspicious

[36] Defendants focus on the high end of this range, but Mr. Rafalski proposes to offer opinions about the entire range produced by application of all of the identified metrics.

orders.[37]

Defendants argue that because Method A and B do not precisely implement the SOM procedures in the Masters' Suspicious Order Monitoring program manual, they are unreliable. However, the algorithms used by Mr. Rafalski and Dr. McCann are based on the D.C. Circuit's language that "[a]s a matter of common sense and ordinary language, orders that deviate from a six-month trend are an 'unusual' and not 'normal' occurrence."[38] Whether the algorithms precisely mirror every operational step in the Masters SOM manual is irrelevant, the algorithms identify orders that deviate from a six-month trend, which the D.C. Circuit has recognized are "unusual" orders. Defendants also complain that Methods A and B are not generally accepted SOMs methods. However, as explained above, the D.C. Circuit held based on the language of the regulation that the *Masters* approach was a reliable method for identifying suspicious orders of unusual size.[39] The logic of this opinion should not change based upon the identity of the registrant.

Moreover, Mr. Rafalski *does not opine* that any particular Defendant was obliged to adopt Method A or Method B. His opinion is that this method provides "a reasonable estimate and an initial trigger and first step for identifying orders of unusual size" and is one of a number of methodologies that could be used to identify suspicious orders.[40] It is simply not feasible, or necessary, for Plaintiffs to develop a suspicious order methodology tailored to each Defendant. It is relevant, and helpful to the trier of fact, to see the number of suspicious orders that *each* methodology would have flagged; together, these analyses provide the Court with a reasonable range of the total number of orders each Defendant should have identified as suspicious and

[37] *See In re National Prescription Opiate Litigation*, 2019 WL 3934490, at *6 (N.D. Ohio, Aug. 20, 2019).

[38] *Masters Pharm.,* 861 F.3d at 216.

[39] *Masters Pharm.,* 861 F.3d at 216 ("orders that deviate from a six-month trend are 'unusual' and not 'normal' occurrence").

[40] Expert App'x, Dkt. # 1097, Exh. 10-A at 50 (Rafalski Rpt.).

investigated. If Defendants truly believed that Methods A and B were inappropriate for their business model or unique circumstances, they could have come forward with alternative reasonable methodologies and applied those methodologies to arrive at their own estimates for suspicious orders. Their failure to do so does not render Methods A and B unreliable. They do not even propose such a method, let alone apply it to ARCOS data to identify any suspicious orders. Given this and the fact that Defendants could potentially have employed other reasonable SOM methodologies, they have failed to establish that Methods A and B do not provide a reliable estimate of the suspicious orders of unusual size that they shipped. In short, Mr. Rafalski's evaluations of Defendants' SOM systems and methodologies for identifying orders are clearly relevant to establishing the magnitude of Defendants' wrongful conduct and the harm it caused. Mr. Rafalski's report establishes that Defendants failed to maintain adequate SOM systems and therefore failed to satisfy their legal obligations under the CSA and applicable regulations. Using Dr. McCann's data analysis, Mr. Rafalski provides an estimate of the suspicious orders that Defendants would have identified had they employed a reliable methodology, including, for example, Methods A and/or B. Taken together, Mr. Rafalski's expert report and Dr. McCann's order analysis establish that Defendants breached their legal duties, provide an estimate of the magnitude of this breach, and are part of Plaintiffs' overall framework of causation and damages in this case.

2. Mr. Rafalski Properly Relied on Dr. McCann's Data Analysis

The fact that Mr. Rafalski did not independently verify or analyze Dr. McCann's results is irrelevant. Indeed, he lacks the data-analysis expertise to do so. Mr. Rafalski is entitled to rely instead on Dr. McCann's expertise and analysis. Pursuant to Federal Rule of Evidence 703, an

expert's testimony may be based on data and conclusions of other experts.[41] Mr. Rafalski did not blindly accept the results: all six of the metrics show that the volume of potentially suspicious orders *was* significant, and confirmed what Mr. Rafalski's analysis had already determined: that Defendants failed to maintain effective controls against diversion. Moreover, Defendants have presumably carefully scrutinized Dr. McCann's work and Defendants have had the opportunity to elicit testimony from Dr. McCann on at least five occasions.[42] Moreover, they have not moved to exclude Dr. McCann's opinions, in effect conceding that Dr. McCann may testify to his results. Under those circumstances, Mr. Rafalski is plainly entitled to rely on them.

3. Mr. Rafalski's Assumptions Were Proper and Provide No Basis to Exclude His Opinions

Finally, Defendants argue that Mr. Rafalski's opinions should be excluded because he improperly assumed that, once an order is flagged as suspicious, all subsequent orders from that same purchaser would also be suspicious and should not be shipped until a due diligence review is completed.[43] This approach is based on the reasonable assumption that once a pharmacy or prescriber has been flagged by a suspicious order monitoring system as a potential locus of diversion, the pharmacy or prescriber should remain flagged (*i.e.*, that all of its orders, or all of his or her prescriptions, for that drug should be treated as suspicious) until the defendant performs due

[41] *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 741 (N.D. Ohio 2014) (expert permitted to testify that statistical analysis of different expert supported his own opinion); *Accessories Mktg., Inc. v. Tek Corp.*, No. C 11-4773 PSG, 2013 WL 1409887, at *1 (N.D. Cal. Apr. 2, 2013). ("experts may rely on the opinion of other experts to formulate their opinions"); *Uncommon, LLC v. Spigen, Inc.*, 305 F. Supp. 3d 825, 845 (N.D. Ill. 2018), *aff'd*, 926 F.3d 409 (7th Cir. 2019) (expert could rely on consumer survey performed by a different expert because the survey itself was supported by a declaration and was reliable and admissible); *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 2d 722, 728 (E.D.N.C. 2007) (citing *Dura Automotive Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 612-14 (7th Cir. 2002)); *see also Williams v. Illinois*, 567 U.S. 50, 89 (2012) (Breyer, J., concurring) ("Experts . . . regularly rely on the technical statements and results of other experts to form their own opinions.").

[42] *See* McCann Dep., May 9 - 10, 2019 (MDL Trial Track One); McCann Dep., Jan. 27, 2020 (New York Opioid Litigation); McCann Test., Aug. 19, 2020 (New York *Frye* Hearing); McCann Dep., July 15, 2020 (State of Ohio, Ex. Rel. v. McKesson, et al.); McCann Dep., Sept. 1, 2020 (Trial Track Two).

[43] *See* Rafalski Mot., Dkt. # 1053 at 14-15.

diligence and establishes that the orders or prescriptions are not likely to be diverted. The assumption used here is substantially identical to the assumption used in the MDL. Defendants made substantially similar objections in the MDL to those raised here, all of which were overruled by Judge Polster, who allowed both Dr. McCann and Mr. Rafalski's opinions to go forward to the fact finder. Finally, Mr. Rafalski's logic has been endorsed by the DEA in its 30(b)(6) deposition testimony, *as well as by some of the Defendants*.[44] Moreover, in *Southwood Pharm., Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007), the DEA made clear that it was investigation of the *customer*, not of an isolated order, that is the heart of effective control against diversion, even if suspicion is triggered by particular orders. Indeed, in that case, the DEA noted that, based on the information Southwood had about certain pharmacies, it should have stopped shipping hydrocodone to them altogether.[45] To the extent that Defendants disagree with Mr. Rafalski's assumptions, they may cross-examine him about them, but their disagreement provides no basis to exclude his opinions.[46]

[44] *See* Ex. 9, DEA 30(b)(6) (Designee Thomas Prevoznik) Dep., April 18, 2019, Dkt. # 1983-10 at 628:24-629:15 (agreeing that if a wholesale distributor gets a flag of a suspicious order, it should block that shipment and terminate all future sales until they can rule out that diversion is occurring); Ex. 10, MCKMDL00409224 at 239 ("Once McKesson deems an order and/or customer suspicious, McKesson is required to act. This means all controlled substance sales to that customer must cease and the DEA must be notified."); Ex. 11, Prevoznik Dep. Exhibit P-8 (Cardinal Health reply brief in *Cardinal Health v. Holder* (D.D.C.) stating "Cardinal Health's policy about which it informed DEA as early as 2009, was that if a customer's order could not be filled because it was suspicious, Cardinal Health would terminate controlled substance sales to the customer and report the termination to the DEA.").

[45] 72 FR at 36501.

[46] The "traditional and appropriate means" of challenging expert testimony are "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof...." *Glass v. Anne Arundel Cty*., 38 F. Supp. 3d 705, 714 (D. Md. 2014), aff'd, 716 F. App'x 179 (4th Cir. 2018). Accordingly, "[t]he court need not determine that the expert testimony is irrefutable or certainly correct." *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006), overruled on other grounds, *U.S. v. Foote*, 784 F.3d 931 (4th Cir. 2015).

D. Defendants' Factual Arguments Regarding West Virginia Board of Pharmacy Evidence are Without Merit and Have No Bearing on Admissibility

Defendants assert a volley of factual arguments in their efforts to preclude Mr. Rafalski's expert opinions in this matter. Not only are these arguments largely red herrings based on misconstruction of the evidence, but these factual disputes – if considered by this Court at all – are relevant only to the weight this Court ultimately gives Mr. Rafalski's opinions and not to admissibility.[47]

Defendants primarily assert that Mr. Rafalski failed to consider "key" documents and testimony related to the West Virginia Board of Pharmacy ("WV BOP"). However, the testimony and documents from the WV BOP do not contradict Mr. Rafalski's opinions. Contrary to Defendants' position that the WV BOP considers a distributor's maintenance of effective controls against diversion prior to issuing or renewing a license to distribute controlled substances, testimony from the WV BOP shows that the WV BOP relied on the DEA to perform such tasks. For example, WV BOP former executive director and general counsel David Potters testified that the WV BOP "did not do anything independently" but instead relied upon the DEA to confirm that that a registrant had designed and was operating a system of effective controls against diversion.[48] Specifically with regard to the Cardinal distribution center in Wheeling, WV, Mr. Potter stated that the WV BOP inspected the center "generally for its safety, cleanliness, et cetera" but did not recall any inspection to determine if Cardinal had a system in place to detect suspicious orders.[49]

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[47] *See Bresler v. Wilmington Trust Company*, 855 F.3d 178, 195–96 (4th Cir. 2017) (disputes regarding significance given to certain alternate factual positions went to weight and not credibility); *Good v. Am. Water Works Co., Inc*., 310 F.R.D. 274, 286 (S.D.W. Va. 2015) (contention that expert witness had relied on standards that had not been adopted as industry standards and that he reached conclusions based on incomplete or selective evidence went to the weight and credibility of expert's opinions, rather than their admissibility)

[48] Ex. 12, David Potters Dep., Aug. 14, 2020 at 36:15-38:15.

[49] *Id*. at 37:16-21.

Defendants' argument similarly falls flat with regard to the WV BOP's "monitoring" of pharmacies.[50] While the WV BOP did inspections of pharmacies looking at things like the cleanliness of the pharmacy, making sure there were not outdated drugs on shelves, and that controlled substances were stored in locked safes and cages, the WV BOP did not monitor "in any way" the number of shipments or size of shipments or quantities of controlled substances that distributors sold to dispensers in West Virginia.[51] Furthermore, the WV BOP did not have access to ARCOS or ARCOS data.[52]

Unlike these extraordinary cases cited by Defendants in which, for example, an expert performed multiple tests and "cherry picked" for inclusion only some test results while excluding others (*Lipitor*), here, Defendants merely offer the types of "disputed evidence of record, [and] questions regarding the factual underpinnings of the expert witness' opinion [that] affect the weight and credibility of the witness' assessment, not its admissibility."[53] These are the very types of "factual issues … more properly settled through '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof'" and do not impinge on the admissibility of Mr. Rafalski's opinions.[54]

In short, none of Defendants' arguments regarding WV BOP evidence have any bearing on the admissibility of Mr. Rafalski's opinions here.

E. Defendants Have Not Challenged Dr. McCann's Expert Opinions and Any Attempt to Challenge Dr. McCann's Analysis Here is Improper

Defendants have not filed a Daubert challenge to the admissibility of Dr. McCann's

[50] Rafalski Mot., Dkt. # 1053 at 17.

[51] *Id*. at 17:1-16 and 23:9-15

[52] *Id.* at 24:4-9.

[53] *Bresler*, 855 F.3d at 195 (quotations and citations omitted).

[54] *Good v. Am. Water Works Co., Inc*., 310 F.R.D. 274, 286 (S.D.W. Va. 2015) (quoting *Daubert*, 509 U.S. at 596.)

testimony and analysis, and Defendants' attempts to challenge Dr. McCann's methods here are improper. Rule 702, by its plain terms, contemplates *Daubert* challenges directed at the opinions of *specific* experts, on an individualized basis.[55] Dr. McCann's role is limited and straightforward: he has the data analysis expertise to apply the metrics identified by Mr. Rafalski to the available data. Dr. McCann's data analysis is relevant and provides the Court with a reasonable range of the total number of orders that Defendants should have identified and investigated. Defendants have not asserted a Daubert challenge with respect to Dr. McCann, and to the degree that Defendants are attempting to exclude Dr. McCann's analysis, their motion is due to be denied.

II. MR. RAFALSKI WAS NOT REQUIRED TO ANALYZE SUSPICIOUS ORDERS OR DETERMINE WHETHER THEY WERE ACTUALLY DIVERTED

Defendants contend that there is a contradiction between Mr. Rafalski's purported opinion that a large proportion of suspicious orders were diverted and the important role of over-prescribing in the opioid epidemic.[56] To begin with, Mr. Rafalski is not expressing an opinion on the number of suspicious orders that were actually diverted. More importantly, there is nothing contradictory about identifying both diversion and over-prescribing as causes of the opioid epidemic. Indeed, it is logical that the two causes operated in tandem, with increased shipments from over-prescribing leading to increased opportunities for diversion. In their capacity as registrants under the CSA, Defendants were charged with maintaining effective controls against diversion.

Defendants repeatedly criticize Mr. Rafalski for failing to review and opine on specific suspicious orders. This type of review is simply not necessary. Mr. Rafalski's report makes clear that in his opinion the metric identified in *Masters* is "a reasonable estimate and an initial trigger

[55] *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *5 (S.D.W. Va. Sept. 29, 2014).

[56] *See* Rafalski Mot., Dkt. # 1053 at 12-13.

and first step for identifying orders of unusual size."[57] Thus, the opinion Mr. Rafalski is offering is that, consistent with the *Masters* decision, Defendants were obligated to investigate all suspicious orders, including those identified by Dr. McCann's analysis, prior to shipping them. Defendants failed to adequately identify suspicious orders and to do the requisite investigation prior to shipping. This investigation is required on all flagged orders. Given the focus of his opinion—Defendants' systemic failure to identify suspicious orders and conduct adequate due diligence in the first place—there was no reason for Mr. Rafalski to review each order separately to determine whether a specific order was in fact suspicious and should not have been shipped. Because each order identified by the algorithm was unusual in size and Defendants' due diligence was inadequate to clear the suspicion of diversion the order was by definition suspicious and should not have been shipped.

Moreover, it is simply untrue that identifying specific suspicious orders is a necessary pre-requisite to assess a Defendant's SOM program. In fact, former DEA deputy director Mr. Ronald Buzzeo, who served as an expert to Mallinckrodt, opined that Mallinckrodt's SOM program complied with relevant CSA and regulatory requirements, without analyzing a single suspicious order. Mr. Buzzeo explained why this was appropriate:

> Q: And in forming this opinion for the 2012 through 2018 time period, did you review any of the orders that Mallinckrodt actually received and shipped?
>
> A: When you're looking at the process and the material, you don't have to actually look at orders. Because looking at an individual order or a thousand orders or something is not really going to tell you whether something is suspicious or not.
>
> So you're looking at the process. You have the process in place to look at the orders to make a determination. That's what I looked at. I looked at the regulation. I looked at the guidance letters, industry experience, my experience, to make that determination.[58]

[57] Expert App'x, Dkt. # 1097, Exh. 10-A at 50 (Rafalski Rep.).

[58] Ex. 13, Ronald Buzzeo Dep., Jun. 28, 2019 at 437:15-438:2.

III. MR. RAFALSKI'S OPINION THAT ORDERS WERE LIKELY TO BE DIVERTED IS RELIABLE

Finally, Defendants challenge Mr. Rafalski's supplemental opinion that the orders for opioids that should have been flagged as suspicious, but that were repeatedly shipped into Cabell and Huntington without sufficient due diligence, were likely to be diverted. Defendants erroneously claim this opinion is unreliable and unsupported. However, Mr. Rafalski's opinion regarding likelihood of diversion is fully consistent with the DEA's longstanding position, and is further based on his education, background, experience, his extensive review of Defendants' documents and conduct, including those evidencing Defendants' lack of effective suspicious order monitoring systems and systemic failures to conduct due diligence, and his review of evidence showing diverted opioids on the streets of Huntington and Cabell County.[59]

Mr. Rafalski's opinion that suspicious opioid orders that were routinely shipped without due diligence were likely to be diverted is supported by the DEA's longstanding position on this same issue. As Mr. Rafalski states in his report, the DEA Diversion Investigator's manual states that where suspicious orders are placed "over extended periods of time, [that] would lead a reasonable person to believe that controlled substances possibly are being diverted."[60] The DEA testified that conclusion was "consistent with the DEA's guidance to the industry since at least 1996."[61] Further, where these suspicious orders are not only placed, but also shipped, the DEA confirmed that "the possibility or potential for [the orders] to be diverted into the illicit market is enhanced…

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[59] Defendants incorrectly assert that Mr. Rafalski's likelihood of diversion opinion is based purely on an algorithm, however, as Mr. Rafalski repeatedly emphasized in his deposition, his likelihood of diversion opinion was based on a totality of his review of Defendants' own documents and communications, including their due diligence records. *See e.g.* Ex. 14, Rafalski Dep., Sept. 11, 2020 at pp. 88-90; 285-289; 300-302. In fact, Mr. Rafalski refused to agree with Defendants that he reached these conclusions by "just purely looking at the string of numbers" from ARCOS. See Rafalski Dep. at pp. 300-306; see also Rafalski Report at 51-52.

[60] *See* Expert App'x, Dkt. # 1097, Exh. 10-A at 17-18 (Rafalski Rpt.); Ex. 15, DEA Diversion Manual, CAH_MDL_PRIORPROD_DEA07_01176247 at CAH_MDL_PRIORPROD_DEA07_01176301.

[61] *See* Ex. 9, Prevoznik Dep., April 18, 2019, at 700:21-701:16.

so… the potential now [for the orders to be diverted] is greater that it's going into the public and is going to affect the public health and safety."[62] In discussions between the DEA Office of Diversion Control and opioid industry representatives, industry representatives acknowledged that suspicious order monitoring systems are based around "algorithms where products are more likely to be diverted."[63] The DEA further testified that where orders are flagged as suspicious "you have a reason to believe that [the orders are]… going to be diverted into the illicit market…."[64] Mr. Rafalski's opinion is further consistent with the *Southwood* opinion in which DEA found, when faced with similar due diligence failures, that "the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was ***the likely diversion*** of millions of dosage units of hydrocodone."[65] Indeed, Congress acknowledges that the purpose of requiring "distributors [to] identify, report, and stop suspicious orders of opioids" is to "reduce diversion rates."[66]

None of the factual arguments raised by Defendants, including those already discussed, undercut the reliability and admissibility of Mr. Rafalski's likelihood of diversion opinion. In the same vein as the WV BOP points discussed above, Defendants' argument that Mr. Rafalski's likelihood of diversion opinions are unreliable based on limited data sources of actual reported diversion is also inapposite. *See* Mot. at 15. The diversion statistic cited by Defendants reflects only the weight of active ingredient reflected in certain reports of theft, loss in transit, or drug seizure, and does not address the likelihood of diversion from dispensing where the federally

[62] *See* Ex. 9, Prevoznik Dep., May 17, 2019, at 891:14 to 892:8.

[63] *See* Ex. 16, MNK-T1_0008504654; Ex. 9, Prevoznik Dep., May 17, 2019, at 1012:14 to 1014:24.

[64] *See* Ex. 9, Prevoznik Dep. May 17, 2019, at 1115:20-1116:2.

[65] *See Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (Dep't of Justice July 3, 2007).

[66] *See* Public Law 115-271, § 3272 (a).

mandated controls are not implemented.[67] Similarly misplaced is Defendants' reliance on a colloquial statement about the number of doctors who are illegally prescribing which, even on its face, doesn't speak to the number of pills or orders likely to be diverted, or even the number or prescriptions written by those doctors. *See* Mot. at 15. Not only do these factual arguments have no direct bearing on the number of suspicious and inadequately investigated shipments of opioids into Cabell and Huntington over the entirety of the relevant time period, but – like the Defendants' arguments regarding the "key" evidence from the WV BOP or Defendants' arguments that the significant increase in opioid shipments might be related to "legitimate medical need" (*see* Mot. at 13) – these points go only toward weight and not admissibility.[68]

CONCLUSION

For the foregoing reasons, this Court should deny in its entirety Defendants' *Daubert* Motion to Exclude the Opinions of James E. Rafalski.

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Respectfully submitted,

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[67] *See* Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2021, https://www.deadiversion.usdoj.gov/fed_regs/quotas/2020/fr0901_2.htm ("DEA gathered data involving employee theft, break-ins, armed robberies, and material lost in transit. DEA also used seizure data by law enforcement nationwide.")

[68] *See Bresler*, 855 F.3d at 195–96; *Good v. Am. Water Works Co., Inc.*, 310 F.R.D. at 286.

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CERTIFICATE OF SERVICE

I certify that on October 23, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system. This filing will also be served on all parties by email to: Track2OpioidDefendants@ReedSmith.com and mdl2804discovery@motleyrice.com.

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